

REMARKS

Claims 61-93 are now pending in the application, with original Claims 1-5, 7-16, 18-44, and 46-60 now having been canceled, original Claims 6, 17, and 45 previously having been canceled, and new Claims 61-93 now having been added. Minor amendments have been made to the Specification and claims to overcome objections to the Specification and rejections of the claims under 35 U.S.C. § 112.

Claim 61 has now been added to better define the subject matter of the recombinant polypeptide in which the defined proteolipid protein “fragment” is attached to a fusion partner. Support for new Claim 61 is found, e.g., in original Claim 1 and at paras. [0082]-[0084] of the Specification (referring herein to paragraph numbers as published in US 2006/0173168). Applicants note that, as used throughout the application in the context of such fusion proteins, a proteolipid protein “fragment” refers to a portion of the recombinant polypeptide that has the defined amino acid sequence of only part of the proteolipid protein, regardless of how the portion is prepared; i.e., the “fragment” need not be obtained by fragmenting a larger polypeptide, but is typically, and preferably, obtained by translation of a recombinant coding sequence.

Claim 62 has now been added to define embodiments of Claim 61 in which the proteolipid protein providing the fragment’s recited amino acid sequence is a mammalian proteolipid protein. Support for new Claim 62 is found, e.g., at paras. [0045] and [0118] of the Specification.

Claim 63 has now been added to define embodiments of Claim 61 in which the sequence of the defined proteolipid protein “fragment” is taken from human

PLP/DM20. Support for new Claim 63 is found, e.g., in original Claim 2. Applicants note that, as used throughout the application, human "PLP/DM20" refers to either one of human PLP or human DM20 in the alternative, as the wild-type amino acid sequence of the C-terminus of both of these proteins is identical.

Claims 64 and 65 have now been added to define embodiments of Claim 61 in which the defined proteolipid protein "fragment" is taken from SEQ ID NO:6. Claims 71, 72, 75, and 76 have now been added to define embodiments in which such a "fragment" is fused to a naturally fluorescent protein or a His-tag. Support for new Claims 64, 65, 71, 72, 75, and 76 is found, e.g., in original Claim 3.

Claim 66 has now been added to define embodiments of Claim 61 in which the fusion partner of the recombinant protein comprises any one of a detectable label, a tag, or a targeting moiety. Support for new Claim 66 is found, e.g., at paras. [0104]-[0105] of the Specification.

Claims 67 and 68 have now been added to define embodiments of Claim 61 in which the fusion partner in the recombinant polypeptide comprises any one of a naturally fluorescent protein, a peptide, an antigen-targeting antibody chain, or a His-tag; or an antigen-targeting single chain Fv; respectively. Support for new Claims 67 and 68 is found, e.g., in original Claim 3 and at para. [0105] of the Specification.

Claim 69 has now been added to define embodiments of Claim 61 in which the fusion partner in the recombinant polypeptide comprises yellow or green fluorescent protein (GFP) or a fluorescent homologue thereof. Support for new Claim 69 is found, e.g., in original Claim 7.

Claim 70 has now been added to define embodiments of Claim 61 in which the fusion partner in the recombinant polypeptide comprises enhanced green fluorescent protein (EGFP) or enhanced yellow fluorescent protein (EYFP). Support for new Claim 70 is found, e.g., in Experiment 1, Table 1, and at para. [0236] of the Specification.

Claims 73 and 74 have now been added to define embodiments of Claim 61 in which that part of the native proteolipid protein that provides the amino acid sequence of the "fragment" comprises a wild-type or mutant amino acid sequence. Support for new Claims 73 and 74 is found, e.g., in original Claim 1.

Claim 77 has now been added to define embodiments of Claim 61 in which the recombinant polypeptide comprises a cleavage site between the "fragment" and the fusion partner thereof. Support for new Claim 77 is found, e.g., at para. [0109] of the Specification.

Claim 78 has now been added to define pharmaceutical compositions that comprise a pharmaceutically acceptable recombinant polypeptide of Claim 61 and a pharmaceutically acceptable carrier. Support for new Claim 78 is found, e.g., in original Claim 41.

New Claims 79-94 have now been added to define methods of use of the recombinant peptide according to new Claim 61. Support for these new claims is found throughout the Specification and in the corresponding original claims shown as follows in parentheses: 79 (46), 80 (47), 81 (47), 82 (50), 83 (48), 84 (49), 85 (51), 86 (52), 87 (53), 88 (54), 89 (55), 90 (56), 91 (57), 92 (59), 93 (58), and 94 (60). Particular support

for the recitation of cells capable of releasing the claimed polypeptides can also be found, e.g., at paragraphs [0037], [0043], [0213], and [0263] of the Specification.

The Examiner is respectfully requested to reconsider and withdraw the rejections in view of the amendments and remarks contained herein. The items raised in the Office Action are addressed below in the order in which they were presented.

ELECTION

Applicants thank the Examiner for consideration of the remarks made in traverse of the Restriction Requirement.

SPECIFICATION

The specification stands objected to for certain informalities. Applicants have amended the specification according to the Examiner's suggestions. Therefore, reconsideration and withdrawal of this objection are respectfully requested.

REJECTIONS UNDER 35 U.S.C. § 112

Claims 1, 2, and 41 stand rejected under 35 U.S.C. § 112, second paragraph, as lacking enablement in that these claims broadly recite PLP fragments and their mutants, and in that Claim 41 defines a pharmaceutical composition that can be useful for, e.g., treating a myelination disorder or neurodegenerative disease.

Claims 1, 2, and 41 stand rejected under 35 U.S.C. § 112, first paragraph, as lacking sufficient written descriptive support in the Specification.

Claims 1, 2, 7, and 41 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point and distinctly claim the subject matter which Applicant regards as the invention, in that terms such as "fragment," "part," and "mutant" did not provide sufficient definition for the amino acid sequences of the claimed peptides; and in that the claims recited "fusion partner."

Claims 1, 2, 7, and 41 have now been replaced with new Claims 61, 63, 69, and 78, respectively. In new Claim 61, the subject matter of Claim 1 is now more clearly presented so as to better define the amino acid sequences of the peptides in terms of their correspondence to SEQ ID NO:6.

Applicants initially note that, as presently claimed, the peptides (i.e. the recited "fragment") have the sequences of "native" proteolipid proteins and that these "native" sequences define a particular genus in which there is little variation. These peptides share the feature of having amino acid sequences of peptides found in live, functioning cells. It is important to note that this defines a distinct subset that is different from all theoretically conceivable "mutants" or "variants" of a peptide sequence, and instead encompasses only native sequences (both wild-type sequences, i.e. those that represent the most common amino acid sequence in the taxon, and mutant sequences, i.e. those that are variants or isoforms found in some taxon members).

Moreover, as shown below (see *In re the Claimed Peptides*), the present application's human PLP/DM20 peptides do share such extensive homology with other proteolipid protein peptides that the presently claimed genus is sufficiently supported by the instant written description. See, e.g., the USPTO "Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶1, 'Written Description' Requirement"

1242(5) O.G. 168 (Jan 30, 2001) (noting that a single disclosed species can support claims to a genus if there are sufficient features among the members of the genus that are shared in common with the species). In addition, Applicants point out that it is this more focused group of peptides that share, or are reasonably expected to share, the biological activity of the disclosed human PLP/DM20 peptides.

Applicants have found that the peptides defined by Claims 61, 63, and 78 do have biological activity that promotes myelin formation and neuronal viability, and that stimulates oligodendrocyte survival and/or differentiation. The *in vitro-in cyto* data disclosed in the present Specification for biological activity of the claimed peptides, e.g., as shown in mixed-cell cultures and in oligodendrocytes-under-stress, correlates well with *in vivo* mixed-cell and stress conditions. The fact that MBP peptides (which are not found as secreted factors *in vivo*) may elicit an immune response does not indicate whether or not a similar response would occur for proteolipid protein peptides (which are found as secreted factors *in vivo*). Thus, Applicants believe that the present showing of *in vitro* activity is sufficient to establish a *prima facie* case for use of the claimed peptides in therapy.

In regard to such a showing of therapeutic usefulness, the present rejection refers to Claim 41 (new Claim 78) as being insufficiently enabled. However, Claim 78 is directed to a pharmaceutical composition, not a method of use. Thus, Applicants respectfully submit that the subject matter of Claim 78 does not lack enablement (see MPEP 2164).

Also, Applicants respectfully submit that the recitation of "fusion partner" is not indefinite as stated in the rejection, but is a standard term of art that refers to any part of

a fusion protein that is co-translated with another part thereof. As presently claimed, any such fusion partner can be co-expressed with a defined proteolipid protein "fragment" as part of the fusion protein.

In re the Claimed Peptides

The amino acid sequences of native proteolipid protein peptides are very highly conserved. For example, as the following comparison table indicates, the PIRP-M-corresponding C-termini of myelin proteolipid proteins from mammals (e.g., primates, rodents, lagomorphs, carnivores, ruminants, marsupials, et al.) amphibians, birds, and reptiles have a remarkably high degree of sequence identity and share about 100% sequence similarity. All of the listed sequences are about the same length and all have a Met residue corresponding to Met1 of SEQ ID NO:6, i.e. the N-terminus of PIRP-M, as well as a Met residue corresponding to Met30 of SEQ ID NO:6, i.e. the N-terminus of PIRP-L.

COMPARISON OF C-TERMINAL SEQUENCES OF MYELIN PROTEOLIPID PROTEINS

1 30
|
1) mygvlpwnafpgkvvcgsnllsicktaefqmtfhlfiaafvgaaatlvslitfmiaatynfavlklmrgrtkf
2) mygvlpwnafpgkvvcgsnllsicktaefqmtfhlfiaafvgaaatlvslitfmiaatynfavlklmrgrtkf
3) mygvlpwnafpgkvvcgsnllsicktaefqmtfhlfiaafvgaaatlvslitfmiaatynfavlklmrgrtkf
4) mygvlpwnafpgkvvcgsnllsicktaefqmtfhlfiaafvgaaatlisltfmiaatynfavlklmrgrtkf
5) mygvlpwnafpgkvvcgsnllsicktaefqmtfhlfiaafvgaaatlisltfmiaatynfavlklmrgrtkf
6) mygvlpwnafpgkvvcgsnllsicktaefqmtfhlfiaafvgaaatlvslitfmiaatynfavlklmrgrtkf
7) mygvlpwnafpgkvvcgsnllsicktaefqmtfhlfiaafvgaaatlvslitfmiaatynfavlklmrgrtkf
8) mygvlpwnafpgkvvcgsnllsicktaefqmtfhlfiaafvgaaatlvslitfmiaatynfavlklmrgrtkf
9) mygvlpwnafpgkvvcgsnllsicktaefqmtfhlfiaaffigaaatlvslitfmiaatynfavlklmrgrtkf
10) mygvlpwnafpgkvvcgsnllsicktaefqmtfhlfiaafvgaaatlvslitfmiaatynfavlklmrgrtkf
11) mygvlpwnafpgkvvcgsnllsicktaefqmtfhlfiaafvgaaatlvslitfmiaatynfavlklmrgrtkf
12) mygvlpwnafpgkvvcgsnllsicktaefqmtfhlfiaafvgaaatlvslitfmiaatynfavlklmrgrtkf
13) mygvlpwnafpgkvvcgsnllsicktsefqmtfhlfiaafvgaaatlvslitfmiaatynfavlklmrgrtkf
14) mygilpwnafpgkvvcgsnllsicktsefqmtfhlfiaafvgaaatlvslvtfiattynfavlrlimrgrtkf
15) mygvlpwnaspgrvvcgqellsicktaefqmtfhlfiaafvgaaatlvalltfiaatynfavlklmrgrtkf
16) mygvlpwnafpgkvvcgtllaicktsefqmtfhlfiaafvgaaatlivalltymvgasnyavrlrvtsdrskf

KEY (Genbank numbers shown)

- 1) P60201 *Homo sapiens*
 - 2) Q5R6E6 *Pongo pygmaeus* (orangutan)
 - 3) XP_001140782 *Pan troglodytes* (chimpanzee)
 - 4) XP_001088537 *Macaca mulatta* (rhesus monkey)
 - 5) Q8HXW7 *Macaca fascicularis* (crab-eating macaque)
 - 6) NP_999139 *Sus scrofa* (pig)
 - 7) NP_035253 *Mus musculus* (mouse)
 - 8) NP_112252 *Rattus norvegicus* (rat)
 - 9) XP_001374483 *Monodelphis domestica* (opossum)
 - 10) P47789 *Oryctolagus cuniculus* (rabbit)
 - 11) CAA08909 *Bos taurus* (cattle)
 - 12) 39025 *Canis familiaris* (dog)
 - 13) CAA43839 *Gallus gallus* (chicken)
 - 14) P47790 *Taeniopygia guttata* (zebra finch)
 - 15) AAW79015 *Gekko japonicus* (gecko lizard)
 - 16) CAA79582 *Xenopus laevis* (frog); with two insertions double-underlined

Moreover, as indicated by the coding sequence comparison table, shown below, the DNA sequence of proteolipid protein genes is also very highly conserved.

COMPARISON OF PROTEOLIPID PROTEIN CODING SEQUENCES

421 tttttgggaa satggatagg acatcccgac sagtttggtt gcatcaccta tgccttggacc
 421 tttttgggaa satggatagg acatcccgac aagtttgggg gcatcaccta tgccttggacc
 422 tttttgggaa satggatagg acatcccgac aagtttgggg gcatcaccta tgccttggacc
 423 tttttgggaa satggatagg acatcccgac aagtttgggg gcatcaccta tgccttggacc

481 ttgtgtgtgc tcctgggtt tgcctgtatc gtgtgtgtt tgcataatttt cttaaacacc
 482 ttgtgtgtgc tcctgggtt tgcctgtatc gtgtgtgtt tgcataatttt cttaaacacc

POLYPYRIMIDINE TRACT

541 tggaccaccc gccaatgtat tgccttcccc agcaagaccc tggcaggatc aggcaggatc
 542 tggaccaccc gccaatgtat tgccttcccc agcaagaccc tggcaggatc aggcaggatc
 543 tggaccaccc gccaatgtat tgccttcccc agcaagaccc tggcaggatc aggcaggatc
 544 tggaccaccc gccaatgtat tgccttcccc agcaagaccc tggcaggatc aggcaggatc

Met³¹

601 ttgtgtgtat ccagaatgtt tgggtgttcc ccatggaaatg ctttccctgg caagggttgt
 601 tgcgtgtat ccggaaatgtt tgggtgttcc ccatggaaatg ctttccctgg caagggttgt
 602 tgcgtgtat ccggaaatgtt tgggtgttcc ccatggaaatg ctttccctgg caagggttgt
 603 tgcgtgtat ccggaaatgtt tgggtgttcc ccatggaaatg ctttccctgg caagggttgt
 604 tgcgtgtat ccggaaatgtt tgggtgttcc ccatggaaatg ctttccctgg caagggttgt

Met³⁰

661 ggctccaaacc ttctgtccat ctgcaaaaaca gctgagttcc aatggaccc tccactgttt
 662 ggctccaaacc ttctgtccat ctgcaaaaaca gctgagttcc aatggaccc tccactgttt
 663 ggctccaaacc ttctgtccat ctgcaaaaaca gctgagttcc aatggaccc tccactgttt
 664 ggctccaaacc ttctgtccat ctgcaaaaaca gctgagttcc aatggaccc tccactgttt

721 attgtgtcat ttgtgggggc ttcagataca ctggttccc tgcacccattt catgattgt
 722 attgtgtcat ttgtgggggc ttcagataca ctggttccc tgcacccattt catgattgt
 723 attgtgtcat ttgtgggggc ttcagataca ctggttccc tgcacccattt catgattgt
 724 attgtgtcat ttgtgggggc ttcagataca ctggttccc tgcacccattt catgattgt

781 gccaatccatc sctttgcgtt cttttaaactc atggggccggag gcaaccaagtt ctga
 782 gccaatccatc sctttgcgtt cttttaaactc atggggccggag gcaaccaagtt ctga
 783 gccaatccatc sctttgcgtt cttttaaactc atggggccggag gcaaccaagtt ctga
 784 gccaatccatc sctttgcgtt cttttaaactc atggggccggag gcaaccaagtt ctga

KEY (Genbank numbers shown)

AJ0006976 <i>Homo sapiens</i>	NM_213974 <i>Sus scrofa</i>
NM_011123 <i>Mus musculus</i>	X53317 <i>Canis familiaris</i>
NM_030880 <i>Rattus norvegicus</i>	X61561 <i>Ovis canadensis</i>
AJ0009913 <i>Bos Taurus</i>	X14632 <i>Macropus leucurus</i> (t codon inserts bold underlined)

In the above coding sequence comparison table, the IRES translation initiation ATG codon for the PIRP-M peptide is shown by a double-underlined Met⁹¹ (that for the PIRP-L peptide is shown by a double-underlined Met³⁰). Also shown upstream from this IRES start codon is one of the polypyrimidine regions conserved among these genes. As described in the Specification of the present application, polypyrimidine regions located upstream from internal ATG start codons have been reported as conserved features in viral IRES elements. Finally, some of the multiple, conserved, upstream GNRA motifs shared among these genes are shown underlined; the presence of multiple upstream, GNRA elements is also reported (as described in the present application) to be a conserved feature in viral IRES elements that are involved in tetraloop formation, and thus IRES function.

Thus, Applicants submit that at both the DNA and amino acid sequence level, from the perspective of one of ordinary skill in the art, the present claims' "native proteolipid protein" and the "part" thereof – whose sequence begins with the residue encoded by the recited IRES start codon – are sufficiently supported and enabled by the Specification as filed, and are recited with definiteness in the present claims.

Finally, in regard to biological activity for therapeutic use, it has been reported that mouse oligodendrocytes expressing such a proteolipid protein can secrete a peptide that has a mouse proteolipid protein C-terminal amino acid sequence, which peptide exerts a beneficial effect of oligodendrocyte proliferation. The present inventors have independently found that human cells expressing human PLP can secrete PIRP-M and/or PIRP-L under conditions of stress; that these peptides have a beneficial biological effect of oligodendrocyte recruitment and/or proliferation, which can facilitate

remyelination and neuronal survival; and that a novel, conserved IRES element is operative in expression of those peptides.

As a result, based upon the disclosure of the present application, there is a strong basis upon which one of ordinary skill in the art could now, for the first time, reasonably conclude (1) that secretion of such a peptide is a common feature to human and animal glial cells generally; (2) that production of such a peptide involves expression starting from the conserved IRES; and (3) that the secreted peptide has biological activity effected pursuant to contact with glial cells *in vivo*. The fact that such peptides are naturally secreted peptides is also important in that their presence in intercellular fluid is a native feature of biological systems, rather than a pathological aberration such as is the extracellular release of MBP, an autoantigen involved in multiple sclerosis and other demyelination-related conditions. See, e.g., C. Husted, "Structural insight into the role of myelin basic protein in multiple sclerosis," *PNAS USA* 103(12):4339-40 (Mar. 21, 2006) (ePubl. Mar. 13, 2006, doi:10.1073/pnas.061002103).

Therefore, Applicants submit that one of ordinary skill in the art would understand (1) the invention defined by the presently amended claims to be enabled by the Specification, and (2) the Specification to provide sufficient written descriptive support for that invention.

Applicants believe that these remarks and amendments overcome the rejections and respectfully request that they be withdrawn.

REJECTION UNDER 35 U.S.C. § 102

Claims 1-4 and 41 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Stoffel et al. (*Hoppe-Seyler's Z. Physiol. Chem.* 363:1117-31 (Sep. 1982)). Stoffel describes that *in vitro* fragmentation of bovine proteolipid protein produced, e.g., a 7.8 kDa fragment (of 7.8 kDa), which was then cleaved by a panel of thermolysin, trypsin, chymotrypsin, and subtilisin, to prepare degradation peptides for sequence analysis. The overlap assemblage of these peptide sequences found that the 7.8 kDa fragment was a 72-residue long C-terminal sequence that differs from the human PIRP-M amino acid sequence by the substitution Leu50Val (see Leu50 of SEQ ID NO:6 in the present application).

This bovine sequence is thereby different from SEQ ID NO:6, not the same sequence as posited by the rejection. In addition, the present claims define a recombinant polypeptide that comprises a fusion partner, fused to the "fragment." Yet, recombinant polypeptides and fusion partners are features that are lacking from Stoffel et al. Thus, the Stoffel reference does not provide all elements as presently claimed.

For these reasons, Applicants believe that the above remarks and amendments overcome the rejection and respectfully request that it be withdrawn.

REJECTION UNDER 35 U.S.C. § 103

Claims 1-4, 7, 8, and 41 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Stoffel et al., as set forth above, in view of Metz et al. (*Somatic Cell & Mol. Genet.* 24:53-69 (1998)), Cha et al. (*Biotech. & Bioeng.* 67:555-74 (2000)), and Pryor et al. (*Protein Exp. & Purif.* 10:309-19 (1997)). The rejection states, "It would

have been obvious to one of ordinary skill in the art...to fuse the [Stoffel] protein with GFP or His for monitoring the expression or location of the protein or purification of the protein. The person of ordinary skill in the art would have been motivated to do so because GFP and His6 have successfully been used in making a fusion protein for purification and quantitative purposes."

Although it is possible for one of ordinary skill in the art to produce a fusion protein by fusing, at the DNA level, a GFP or His6 fusion partner with a desired target peptide, Applicants respectfully point out that none of the cited references describes or suggests that Stoffel's 7.8 kDa fragmented piece of bovine proteolipid protein is an expressed peptide, i.e. is expressed other than as part of that whole protein. The subject matter of the current claims, however, does not include whole proteolipid proteins, but instead recites peptides having defined, native amino acid sequences of IRES-expressed portions of such proteolipid proteins.

Applicants also respectfully point out that none of the cited references describes or suggests that such a fragment has any biological activity at all. For example, Stoffel et al. report no naturally occurring peptide whose amino acid sequence is the 72-amino acid long sequence of their 7.8 kDa fragment. Stoffel et al. do not describe, suggest, or hint at the expression of such a molecule, nor any of the biological properties or utility such a molecule might possess, nor whether any molecule exists that might have such properties/utility.

The mere fact that Stoffel describes the amino acid sequence of a C-terminal fragment of a proteolipid protein does not make Applicants' claimed invention obvious. See MPEP 2144.09, which states

If the prior art does not teach any specific or significant utility for the disclosed compounds, then the prior art is not sufficient to render structurally similar claims *prima facie* obvious because there is no motivation for one of ordinary skill in the art to make the reference compounds, much less any structurally related compounds. *In re Stemniski*, 444 F.2d 581, 170 USPQ 343 (CCPA 1971).

Where structurally similar "prior art compounds 'cannot be regarded as useful' for the sole use disclosed [by the reference], ...a person having ordinary skill in the art would lack the 'necessary impetus' to make the claimed compounds." *In re Albrecht*, 514 F.2d 1389, 1396, 185 USPQ 585, 590 (CCPA 1975).

Stoffel does not describe any specific or significant utility for the 7.8 kDa fragment, and none of the Cha, Pryor, or Metz references provides what is lacking from Stoffel. Consequently, one of ordinary skill in the art would have had no apparent reason to select a Stoffel fragment to monitor for expression, location, purification, or quantitation. This means that one of ordinary skill in the art would have had no apparent reason to combine such a Stoffel fragment with a Cha GFP, a Pryor His6, and/or a Metz IRES element. (See, e.g., *KSR Int'l Co. v. Teleflex, Inc.*, No. 04-1350 (U.S. Supreme Court, Apr. 30, 2007) and the May 3, 2007 Memorandum thereon from USPTO Dep. Comm'r M.A. Focarino to Technology Center Directors.)

For all of these reasons, Applicants respectfully submit that a *prima facie* case of obviousness has not been raised, and that the subject matter as defined by the present claims would not have been obvious to one of ordinary skill in the art from the cited references. Applicants believe that these remarks overcome the rejection and respectfully request that it be withdrawn.

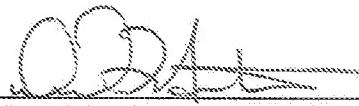
CONCLUSION

Applicants submit that a complete response has been made to the outstanding Office Action and that all of the stated grounds of rejection have been overcome thereby. Applicants therefore respectfully request that the Examiner reconsider and withdraw all presently outstanding rejections and consider the present application to be in condition for allowance. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (248) 641-1600.

Respectfully submitted,

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